

# Exhibit 49

# Quarterly Compliance Report to the Board of Directors 1Q2013

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Bert Weinstein  
Vice President, Corporate Compliance  
April 10, 2013



U.S. - 94

# Corporate Integrity Agreement - Closed



## Purdue's CIA Officially Closed

From Letter dated January 24<sup>th</sup>, Office of Inspector General, HHS:

We have reviewed Purdue Pharma LP's (Purdue's) Fifth Annual Report and the correspondence and information provided subsequent to Purdue's submission of the Fifth Annual Report. Based on our review of all of this information, it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) between the Office of Inspector General (OIG) of the Department of Health and Human Services and Purdue during the fifth annual reporting period. This letter confirms that we have no further questions regarding Purdue's Fifth Annual Report and that the term of the Purdue CIA has now concluded.



U.S. - 95

# **Key Compliance Issues Seen in Q1**

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## **Field Sales Call Note Reviews**

- Monthly call note reviews now being completed on a 30 day cycle
- Reviewing 10% of approx. 90K call notes generated monthly
- Faster spotting of issues, e.g.,
  - Pro-active discussion of OxyContin reformulation (not permitted)
  - Quality of life / implied superiority claims (not permitted)

## **Sales Discipline Committee**

- Completing call note reviews this fast has enhanced effectiveness of Sales discipline process
- Corporate Compliance has been able to spot trends and provide remediation more proactively and effectively



# **Key Compliance Issues Seen in Q1**



## **Speaker Programs – “Monitoring Forms”**

- Issue – Speaker Monitoring Forms are critical to proper program compliance - not being submitted in a timely fashion
- Solution – Ongoing monthly monitoring by Corporate Compliance along with Sales Management training on requirements and impact- no longer an issue

## **Field Contact Reports**

- Issue – Managers not completing documented work sessions every 90 days – SOP requirement
- Solution – As part of revised Sales SOP, new work session requirement changed from 8 days annually to 2 days per quarter- will be remedied with monthly monitoring and reporting



# **“Priority Risks” Addressing in 2013**



**Price Reporting** – Government price and rebate reporting accurate and timely - with increased focus on enforcement

**Site Monitoring** - Study Manager review of Monitoring Reports and clinical trial oversight

- There are thousands of clinical trial sites, with consequent multiplication of risk; we must have accuracy and integrity of data for NDA filings
- Drug diversion issues at clinical trial sites - need to be remediated



# **“Priority Risks” Addressing in 2013**

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## **Managed Care**

- Increased government scrutiny
- Negotiations with Managed Care Organizations
- Managed Care promotional activities that touch on government lives

## **Appropriate Promotion**

- Intermezzo promotion by ASF and ISF
  - Risk – promotion of co-morbid conditions
  - Risk - FDA guidance on zolpidem and gender dosing
- OxyContin promotion, especially with regard to abuse potential
  - Risk – Comparative statements: i.e., reformulation vs. generic, reformulation vs. original
- OxyContin forthcoming “label change”



# **“Priority Risks” Addressing in 2013**

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## **Sunshine Act** - Maintaining competitive advantage *and* remaining compliant

- Final regulations pose special challenges in capturing clinical data
- How good are our data sources?
- Data mining by competitors and consultants of information made public

## **Quality Investigations**

- Risk in length of time to complete Quality investigations
- Need to incorporate learnings from Quality investigations and implement best practices. Need clear accountability
- New Compliance Scorecard element tracks and scores time to close investigations





# Sunshine Act - Summary

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To Provide public reporting on spend by pharma and device manufacturers on physicians and teaching hospitals

**Why?** To allow patients to make decisions about who they use as their provider

**What?** Any payment or transfer of value - anything with “discernible economic value”

## **Upcoming Dates**

- **August 1, 2013** – begin tracking transfers of value
- **March 31, 2014**– first disclosure report is due to CMS
- **September 30, 2014** – CMS will make information publicly available through a searchable website
- Annual reporting thereafter



# Scope of Sunshine Act Payments

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Examples of payments/other transfers of value to be reported:

- Meals during office visits or speaker programs
- “Educational” items and materials, if not for patient use
- Consulting fees and related expenses (inc. travel, lodging, meals)
- Speaker fees (inc. travel, lodging, meals)
- Educational and research grants
- Payments and in-kind items related to research and development activities (but with delayed publication provision for payments related to products in development)
- Exhibits, Conventions, Product Theaters



# Sunshine Act Data Requirements

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For each Physician or Teaching Hospital with spend, must report the following information (not exhaustive list):

- First Name, Last Name, Middle Initial, suffix
- Primary business address
- Specialty
- National Provider Identifier #
- Amount of payment
- Dates payment made
- Form of payment
- State License Number
- State(s) of Licensure
- Physician designation (e.g., MD, DO)
- Nature and purpose of payment
- Name of the product(s) to which the payment relates
- NDC number(s) for each product to which the payment relates



# Sunshine Act Data Requirements

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A new data collection system has been built to aggregate all Purdue data required for Sunshine Act and State law reporting requirements:



# Further Sunshine Act Provisions

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## Dispute Resolution

- Covered recipients have opportunity to review data at least 45 days before data made public
- Covered recipients may initiate a dispute
- If disputed, manufacturer and the recipient must attempt to resolve the dispute, within 15 days
- If dispute not resolved, CMS will post data as reported by the manufacturer and note it is disputed

## Civil Monetary Penalties

Manufacturers are subject to civil money penalties for failing timely to accurately and completely report data





# FYI BACKUP SLIDE



U.S. - 106

# Compliance Charter Amendment

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FYI – The Compliance Department activities are carried out, in part, pursuant to a 2005 Board-approved Charter. The Charter was amended in 2007 to account for certain CIA requirements. With closure of the CIA, we have broadened the activities of Purdue's Compliance Committee, and modified the membership from the CIA-required membership to account for the new role of the Committee.

